

have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, for example at page 16, lines 5-14, and in the original claims. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 1, 2 and 10-23 are pending in the application.

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have cancelled non-elected claims 3-9 from the application.

**1. *Rejection of Claims 1,2 and 10-21 under 35 U.S.C. §112, 1<sup>st</sup> Paragraph: Written Description***

Claims 1, 2 and 10-21 have been erroneously rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being described in the specification “in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action at page 3. The Examiner does not dispute that Applicants had possession of and have adequately described the claimed SEQ ID NOs. *Id.* at page 4. However, the Examiner contends that the specification allegedly “provides insufficient written description to support the genus encompassed by the claim.” *Id.*

As Applicants have previously stated, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art, *e.g.*, a molecular biologist, would, after reading the present specification, understand that Applicants had possession of SEQ ID

NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619, complements and variations thereof, as well as the enzymes they encode, and therefore, the claimed invention.

The Examiner contends “[a]s the claims recite open claim language, they are also directed to encompass gene sequences, corresponding sequences from other species, mutated sequences, polymorphic sequences, exogenous sequences, and so forth”. Office Action at page 4. According to the Examiner, “[n]one of these sequences meet the written description provision of 35 U.S.C. § 112, first paragraph.” *Id.* This is not a proper basis for a written description rejection of a “comprising” claim. If it was, every “comprising” claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

The Examiner acknowledges that the specification describes gene sequences, corresponding sequences from other species, mutated sequences, polymorphic sequences, exogenous sequences, and so forth (*see, e.g.*, specification at pages 25-35). See Office Action at page 4. The specification also describes, for example, nucleic acid molecules comprising nucleic acid sequences having conservative substitutions (specification at page 48, line 14 through page 50, line 6), fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (specification at page 59, lines 4-15), plant homologue proteins (specification at page 59, line 16 through page 60, line 6), site directed mutagenesis of the claimed nucleic acid molecules (specification at page 87, line 12 through page 89, line 3), vectors comprising the claimed nucleic acid molecules and methods of transforming plants (specification 93, line 1 through page 107, line 19) and construction of cDNA libraries using the claimed nucleic acid molecules (specification at page 152, line 13 through page 222, line 7 (Examples 1-3)). Despite the numerous variations of the claimed nucleic acid molecules described in the present specification, the Examiner maintains that one skilled in the art could not “readily envision members of the genus encompassed by the claim.” Office Action at page 4.

The Examiner further states that one skilled in the art "would reasonably doubt that sequence similarity alone is sufficient to predict whether the biological and enzymatic activity of the claimed subject matter is the same as that of the prior art." Office Action at page 5. In support of this proposition, the Examiner relies on Baker *et al.* (Science (10/5/2001), vol. 294, pages 93-96). In response, Applicants contend that this article is directed to the controversy in the art in general over prediction of function based on homology alone, but does not take into consideration Applicants' disclosure.

The present specification discloses that the claimed SEQ ID NOs exhibit a range from about 44% to about 72% sequence identity with a nucleic acid sequence known to encode a maize or soybean phosphogluconate pathway enzyme. *See* Table A. According to the teachings in Baker *et al.*, this is considered a "high-accuracy" comparative model. *See* Baker *et al.*, at page 93. Moreover, Example 4 delineates the methods used to generate the homology in Table A. The Examiner has offered no evidence to demonstrate, in light of Applicants' disclosure, why one of ordinary skill in the art would reasonably doubt that a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 or the complements thereof would encode a maize or soybean phosphogluconate pathway enzyme and, as such, has not met the burden to impose a written description rejection.

Furthermore, the Examiner appears to assert that each nucleic acid molecule within a claimed genus must be described by its complete structure. Office Action at page 5. This assertion is unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example the nucleotide sequences of SEQ ID NO: 1, SEQ ID NO: 4, SEQ ID NO: 14, etc. The respective common structural feature (the nucleotide sequences of SEQ ID NOs: 1, 4, 14,

27, 225, 298, 311, 356, 569, and 619) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1.<sup>1</sup> If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of that claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, claims 1, 2 and 10-21 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and reversal are respectfully requested.

## ***2. Rejection of Claims 1 and 2 under 35 U.S.C. §112, 2<sup>nd</sup> Paragraph: Indefiniteness***

The Examiner erroneously rejected claims 1 and 2 as “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Office Action at page 6. According to the Examiner, for claim 1 “[i]t is unclear whether applicant intends that any one of the SEQ ID NO’s correlates with all of the recited enzymes, or intends for each SEQ ID NO: to correlate with a single enzyme. If the latter, then it is further unclear which SEQ ID NO: is intended to correlate with each enzyme.” *Id.* Finally, although the Examiner contends that one skilled in the art “could certainly ascertain whether a nucleic acid hybridizes to another”, the claims are

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<sup>1</sup> The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 4, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 4. *See, e.g.,* claim 13.

allegedly indefinite because one skilled in the art would not know "which enzyme or enzymes the nucleic acid must also encode". *Id.* at 7.

The application of 35 U.S.C. § 112, second paragraph, to claims 1 and 2 is inappropriate. The essential inquiry pertaining to the requirement for clarity and precision of claim language is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Furthermore, definiteness of claim language is not analyzed in a vacuum, but in light of Applicants' disclosure, the teachings of the prior art, and the claim interpretation that would be given by one of ordinary skill in the art at the time the invention was made. *See* MPEP § 2173.02, at page 2100-194.

In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the claims must be considered as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). Thus, the test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). A person of ordinary skill in the art would understand the metes and bounds of claims 1 and 2 when read in light of the disclosure of the specification.

Upon reading Applicants' disclosure, one of ordinary skill in the art, *e.g.*, a molecular biologist, would understand what Applicants regard as the invention. The specification describes, for example, which SEQ ID NOs encode which enzymes at page 15, line 18 through page 20, line 4; at page 51, line 1 through page 52, line 3; and in Table A. One of ordinary skill in the art after reading the present disclosure would clearly understand which enzyme correlates with each SEQ ID NO. As such, the rejection under 35 U.S.C. § 112, second paragraph, is improper. Reconsideration and withdraw of this rejection is respectfully requested.

### **3. The Rejections Under 35 U.S.C. § 102**

Claims 1 and 10 were erroneously rejected under 35 U.S.C. § 102(a) over NCBI accession number AF037030. According to the Examiner, AF037030 “teaches an mRNA/cDNA sequence which encodes a corn 6-phosphogluconate dehydrogenase and is 95% identical/complementary to instant SEQ ID NO: 4 [sic – 14].” Office Action at page 7. Although the Office Action admits that “[t]he Office does not have the facilities to carry out hybridization experiments”, the Examiner maintains that “one skilled in the art would reasonably expect a sequence with 95% identity/complementarity to SEQ ID NO: 14 to hybridize to SEQ ID NO: 14 or its complement.” *Id.* at 8.

This reference does not anticipate the present claims. For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). AF037030 does not teach every element of the claimed invention.

The Examiner admits that the AF037030 reference does not disclose the sequence of SEQ ID NO: 14, but rather contends that one of ordinary skill in the art would reasonably expect AF037030 to hybridize to SEQ ID NO: 14 under the conditions recited in the claims. *See* Office Action at pages 7-8. The examiner presents no evidence to support this position. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicants to provide evidence that AF037030 would not hybridize to the complement of SEQ ID NO: 14 under the claimed hybridization conditions. This is not the law.

Furthermore, a rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Examiner has submitted no evidence that AF037030 was available to the public prior to Applicants’ filing date. The Examiner apparently relies on the date the nucleotide sequence was submitted to the NCBI database (*i.e.*, November 26, 1998) to establish the reference date under §102(a). However, there

is no evidence that the sequence was published or otherwise available to the public prior to Applicants' filing date.

Although Applicants strenuously disagree with the rejection of claims 1 and 10 under 35 U.S.C. § 102(a), to facilitate prosecution claims 1 and 10 have been amended. As such, the rejection of claims 1 and 10 under 35 U.S.C. § 102(a) over AF037030 has been rendered moot.

Claim 10 has also been erroneously rejected under 35 U.S.C. § 102(a) over UCHIMIYA (NCBI accession number D43256). According to the Examiner, D43256 is 74.6% identical/complementary to SEQ ID NO: 619 and "would reasonably be expected by one skilled in the art to hybridize to SEQ ID NO: 619 or its complement under the hybridization conditions recited in claim 10". Office Action at page 8.

This reference does not anticipate the present claims. As stated above, for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.

The Examiner contends that D43256 anticipates claim 10 because D43256 "would reasonably be expected by one skilled in the art to hybridize to SEQ ID NO: 619 or its complement under the hybridization conditions recited in claim 10". Office Action at page 8. However, the Examiner presents no evidence to support this position. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicants to provide evidence that D43256 would not hybridize to SEQ ID NO: 619 or its complement under the claimed hybridization conditions. This is not the law.

Furthermore, a rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Examiner has submitted no evidence that D43256 was available to the public prior to Applicants' filing date. The Examiner apparently relies on the date the nucleotide sequence was submitted to the NCBI database (*i.e.*, May 4, 1998) to establish the reference date under §102(a). However, there is no evidence that the sequence was published or otherwise available to the public prior to Applicants' filing date. Thus, the rejection of claim 10 under 35 U.S.C. § 102(a) over D43256 is improper and should be withdrawn.

Claims 1 and 10 have also been erroneously rejected under 35 U.S.C. § 102(a) over MARTIN (NCBI accession number AJ000265). According to the Examiner, AJ000265 teaches “a sequence encoding a glucose-6-phosphate isomerase which is 66.4% identical to SEQ ID NO: 619, with a local similarity of 79%.” Office Action at page 9.

This reference does not anticipate the present claims. As stated above, for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.

The Examiner admits that the AJ000265 reference does not disclose the sequence of SEQ ID NO: 619, but rather speculates that AJ00265 would “hybridize to the complement of SEQ ID NO: 619 under the hybridization conditions recited in the claims.” Office Action at page 9. However, the Examiner presents no evidence to support such conjecture. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicants to provide evidence that AJ000265 would not hybridize to SEQ ID NO: 619 or its complement under the claimed hybridization conditions. This is not the law.

Moreover, AJ000265 was isolated from *spinacia oleracea*, and does not disclose a nucleic acid molecule that encodes a maize or soybean phosphogluconate pathway enzyme, as recited in claim 1. Because the Examiner has not demonstrated that the chemical disclosed in the AJ000265 reference would hybridize to SEQ ID NO: 619 under the conditions recited in claims 1 and 10, every element of the claimed invention has not been identically shown in the reference. *See Diversitech Corp.*, 850 F.2d at 677, 7 U.S.P.Q.2d at 1317.

Furthermore, a rejection under 35 U.S.C. § 102(a) is only proper if, *inter alia*, an anticipatory reference is available publicly. The Examiner has submitted no evidence that AJ000265 was available to the public prior to Applicants’ filing date. The Examiner apparently relies on the date the nucleotide sequence was submitted to the NCBI database (*i.e.*, August 25, 1998) to establish the reference date under §102(a). However, there is no evidence that the sequence was published or otherwise available to the public prior to

Applicants' filing date. Thus, the rejection of claims 1 and 10 under 35 U.S.C. § 102(a) over AJ000265 is improper and should be withdrawn.

Claims 1 and 10 have also been erroneously rejected under 35 U.S.C. § 102(b) over KATSURADA (NCBI accession number AB007907). According to the Examiner, AB007907 "teaches a cDNA/mRNA which is encodes [sic] a soybean 6-phosphogluconate dehydrogenase and is 59.5% identical to SEQ ID NO: 27 with a local similarity to SEQ ID NO: 27 of 80.3%." Office Action at page 9.

This reference does not anticipate the present claims. As stated above, for a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.

The Examiner admits that the AB007907 reference does not disclose the sequence of SEQ ID NO: 27, but rather conjectures that "[a] sequence with 59.5% identity and a local similarity of at least 80% would be reasonably expected by one skilled in the art to hybridize to SEQ ID NO: 27 or its complement under the conditions recited in the claims". *Id.* Such conjecture is insufficient to support a rejection.

The Examiner presents no evidence to support this position. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicants to provide evidence that AB007907 would not hybridize to SEQ ID NO: 27 or its complement under the claimed hybridization conditions. This is not the law.

Because the Examiner has not demonstrated that the chemical disclosed in the AB007907 reference would hybridize to SEQ ID NO: 27 under the conditions recited in claims 1 and 10, every element of the claimed invention has not been identically shown in the reference. *See Diversitech Corp.*, 850 F.2d at 677, 7 U.S.P.Q.2d at 1317. As such, the rejection of claims 1 and 10 under 35 U.S.C. § 102(b) over AB007907 is improper and should be withdrawn.

## Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe that any fees in addition to those provided for in the accompanying documents, are due at this time. However, if any fees under 37 C.F.R. 1.16 or 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2387, referencing docket number 16517.216.

Respectfully submitted,



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**Marked-up Version of Amended Claims**

1. A substantially purified nucleic acid molecule that encodes a maize or soybean phosphogluconate pathway enzyme, wherein said maize or soybean phosphogluconate pathway enzyme is selected from the group consisting of:

- (a) glucose-6-phosphate-1-dehydrogenase;
- [**(b)** **6-phosphogluconate dehydrogenase;**]
- [**(c)**] [**(b)** D-ribulose-5-phosphate-3-epimerase;]
- [**(d)**] [**(c)** ribose-5-phosphate isomerase;]
- [**(e)**] [**(d)** transketolase;]
- [**(f)**] [**(e)** transaldolase; and]
- [**(g)**] [**(f)** phosphoglucoisomerase;]

wherein the substantially purified nucleic acid molecule comprises a nucleic acid sequence that hybridizes under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, [14,] 27, 225, 298, 311, 356, 569, 619 and [**the**] complements thereof.

2. The substantially purified nucleic acid molecule according to claim 1, wherein said substantially purified nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, [14,] 27, 225, 298, 311, 356, 569, and 619.

10. An isolated nucleic acid molecule comprising a sequence that hybridizes under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, [14,] 27, 225, 298, 311, 356, 569, 619 and complements thereof.